IN THE SPECIFICATION:

Please amend paragraph **[0015]** of the specification as follows:

[0015] As disclosed in references in the photographic arts, for example in U.S. Patent No. 5,780,109 to Yapel *et al.* and U.S. Patent No. 5,861,195 to Bhave *et al.*, which are incorporated herein by reference, slot coating, slide coating, and curtain coating coaters "have been used extensively since the 1950's in the photographic and related industries for coating aqueous photographic emulsions." (Yapel, col.1, lns. 22-24.) For example, a slide coating method or apparatus has been used in the photographic arts to deposit multiple layers of photothermographic film coating solutions to a paper-based or polymeric film-based substrate or web. However, such slot, slide, and curtain coating processes have not been previously proposed or used to coat surfaces of medical devices, such as coating the external surface of a stent or stent graft. Nor have such coating processes been previously proposed or used to deposit a coating material with a therapeutic agent.

Please amend paragraph **[0017]** of the specification as follows:

[0017] Alternate embodiments of the present invention also permit simultaneous application of multiple layers of coating material by using a slide coating head or curtain coating head. These methods of the present invention are time efficient and cost effective because they facilitate the uniform application of multiple layers of coating materials in a single coating process step without requiring any intermediate drying step between ~~application~~ applications of coating layers. This results in higher process efficiency. Further, slide coating heads permit the coating of high viscosity coating solutions as well as low viscosity coating solutions.

Please amend paragraph **[0030]** of the specification as follows:

[0030] In Figure 3, an apparatus for coating a medical device in accord with another embodiment of the present invention is shown. In this embodiment, generally designated as 50, a slide coating head 60 may be used to deposit multiple layers of superposed coating material (generally, multi-layer coating material 70) onto an external surface 13 of medical device 11. This apparatus permits uniform coating of multiple layers of coating in a single coating process step without requiring any intermediate drying step between ~~application~~ applications of coating layers. Each coating solution may be the same or a different coating solution. The individual layers of coating material are dispelled from slots 91, 92, 93, 94, each of which have inlets and outlet orifices (shown respectively as 98 and 97 for slot 94 only).

Please amend paragraph **[0039]** of the specification as follows:

[0039] In Figure 4, an apparatus for coating a medical device having a surface in accord with another embodiment of the present invention is shown. In this embodiment, generally designated as 100, a curtain coating head 110 may be used to deposit multiple layers of superposed coating material (generally, multi-layer coating material 120) onto an external surface of medical device 140. The curtain head can also be adapted to deposit a single layer of coating material. This apparatus permits uniform coating of multiple layers of coating in a single coating process step without requiring any intermediate drying step between ~~application~~ applications of coating layers. Each coating solution may be the same or a different coating solution.

Please amend paragraph **[0041]** of the specification as follows:

[0041] The medical devices used in conjunction with the present invention include any device amenable to the coating processes described herein. The medical device, or portion of the medical device, to be coated or surface modified may be made of metal, polymers,

ceramics, composites or combinations thereof. Whereas the present invention is described herein with specific reference to a vascular stent, other medical devices within the scope of the present invention include any devices which are used, at least in part, to penetrate the body of a patient. Examples include implantable devices such as vascular grafts, stent grafts, biliary stents, colonic stents, bronchial/pulmonary stents, esophageal stents, ureteral stents, aneurysm filling coils and other coiled coil devices, catheters, needle injection catheters, blood clot filters, ~~trans-myocardial~~ trans-myocardial revascularization ("TMR") devices, percutaneous myocardial revascularization ("PMR") devices etc., as are known in the art, as well as devices such as hypodermic needles, soft tissue clips, holding devices, and other types of medically useful needles and closures. Any exposed surface of these medical devices may be coated with the methods and apparatuses of the present invention.

Please amend paragraph **[0042]** of the specification as follows:

[0042] The coating materials used in conjunction with the present invention are any desired, suitable substances. In some embodiments, the coating materials comprise therapeutic agents, applied to the medical devices alone or in combination with solvents in which the therapeutic agents are at least partially soluble or dispersible or emulsified, and/or in combination with polymeric materials as solutions, dispersions, suspensions, ~~latices~~ lattices, etc. The solvents may be aqueous or non-aqueous. Coating materials with solvents may be dried or cured, with or without added external heat, after being deposited on the medical device to remove the solvent. In another embodiment, the coating materials comprise a solvent solution that does not include therapeutic agents (e.g. a barrier layer coating). The term "therapeutic agents" include pharmaceutically active compounds, nucleic acids with and without carrier vectors such as lipids, compacting agents (such as histones), virus, polymers, proteins, and the

like, with or without targeting sequences. The coating on the medical devices may provide for controlled release, which includes long-term or sustained release, of a bioactive material.

Please amend paragraph **[0043]** of the specification as follows:

[0043] Specific examples of therapeutic or bioactive agents used in conjunction with the present invention include, for example, pharmaceutically active compounds, proteins, oligonucleotides, ribozymes, anti-sense genes, DNA compacting agents, gene/vector systems (*i.e.*, anything that allows for the uptake and expression of nucleic acids), nucleic acids (including, for example, recombinant nucleic acids; naked DNA, cDNA, RNA; genomic DNA, cDNA or RNA in a non-infectious vector or in a viral vector which may have attached peptide targeting sequences; antisense nucleic acid (RNA or DNA); and DNA chimeras which include gene sequences and encoding for ferry proteins such as membrane translocating sequences ("MTS") and herpes simplex virus-1 ("VP22")), and ~~viral, liposomes~~ viral liposomes and cationic polymers that are selected from a number of types depending on the desired application. For example, biologically active solutes include anti-thrombogenic agents such as heparin, heparin derivatives, urokinase, and PPACK (dextrophenylalanine proline arginine chloromethylketone); prostaglandins, prostacyclins/prostacyclin analogs; antioxidants such as probucol and retinoic acid; angiogenic and anti-angiogenic agents; agents blocking smooth muscle cell proliferation such as rapamycin, angiopeptin, and monoclonal antibodies capable of blocking smooth muscle cell proliferation; anti-inflammatory agents such as dexamethasone, prednisolone, corticosterone, budesonide, estrogen, sulfasalazine, acetyl salicylic acid, and mesalamine, lipoxygenase inhibitors; calcium entry blockers such as verapamil, diltiazem and nifedipine; antineoplastic / antiproliferative / anti-mitotic agents such as paclitaxel, 5-fluorouracil, methotrexate, doxorubicin, daunorubicin, cyclosporine, cisplatin, vinblastine,

vincristine, colchicine, epothilones, endostatin, angiostatin, Squalamine, and thymidine kinase inhibitors; L-arginine; antimicrobials such as triclosan, cephalosporins, aminoglycosides, and ~~nitorfurantoin~~ nitrofurantoin; anesthetic agents such as lidocaine, bupivacaine, and ropivacaine; nitric oxide (NO) donors such as ~~lisidomine~~ linsidomine, molsidomine, NO-protein adducts, NO-polysaccharide adducts, polymeric or oligomeric NO adducts or chemical complexes; anti-coagulants such as D-Phe-Pro-Arg chloromethyl ketone, an RGD peptide-containing compound, heparin, antithrombin compounds, platelet receptor antagonists, anti-thrombin antibodies, anti-platelet receptor antibodies, enoxaparin, hirudin, ~~Warafin~~ Warfarin sodium, Dicumarol, aspirin, prostaglandin inhibitors, platelet inhibitors and tick antiplatelet factors; interleukins, interferons, and free radical scavengers; vascular cell growth promoters such as growth factors, growth factor receptor antagonists, transcriptional activators, and translational ~~promotors~~ promoters; vascular cell growth inhibitors such as growth factor inhibitors (*e.g.*, PDGF inhibitor - Trapidil), growth factor receptor antagonists, transcriptional repressors, translational repressors, replication inhibitors, inhibitory antibodies, antibodies directed against growth factors, bifunctional molecules consisting of a growth factor and a cytotoxin, bifunctional molecules consisting of an antibody and a cytotoxin; Tyrosine kinase inhibitors, chymase inhibitors, *e.g.*, Tranilast, ACE inhibitors, *e.g.*, Enalapril, MMP inhibitors, *(e.g.,* Ilomastat, METASTAT®), GP IIb/IIIa inhibitors (*e.g.,* INTEGRILIN®, abciximab), ~~seratonin antagnonist~~ serotonin antagonist, and 5-HT uptake inhibitors; cholesterol-lowering agents; vasodilating agents; agents which interfere with ~~endogeneus~~ endogenous vascoactive mechanisms; survival genes which protect against cell death, such as anti-apoptotic Bcl-2 family factors and Akt kinase; and combinations thereof; and beta blockers. These and other compounds may be added to a coating solution, including a

coating solution that includes a polymer, using similar methods and routinely tested as set forth in the specification. Any modifications are routinely made by one skilled in the art.

Please amend paragraph [0044] of the specification as follows:

[0044] Polynucleotide sequences useful in practice of the invention include DNA or RNA sequences having a therapeutic effect after being taken up by a cell. Examples of therapeutic polynucleotides include anti-sense DNA and RNA; DNA coding for an anti-sense RNA; or DNA coding for tRNA or rRNA to replace defective or deficient endogenous molecules. The polynucleotides of the invention can also code for therapeutic proteins or polypeptides. A polypeptide is understood to be any translation product of a polynucleotide regardless of size, and whether glycosylated or not. Therapeutic proteins and polypeptides include as a primary example, those proteins or polypeptides that can compensate for defective or deficient species in an animal, or those that act through toxic effects to limit or remove harmful cells from the body. In addition, the polypeptides or proteins that can be incorporated into the polymer coating, or whose DNA can be incorporated, include without limitation, angiogenic factors and other molecules competent to induce angiogenesis, including acidic and basic fibroblast growth factors, vascular endothelial growth factor, hif-1, epidermal growth factor, transforming growth factor α and β, platelet-derived endothelial growth factor, platelet-derived growth factor, tumor necrosis factor α, hepatocyte growth factor and insulin like growth factor; growth factors; cell cycle inhibitors including CDK inhibitors; anti-restenosis agents, including p15, p16, p18, p19, p21, p27, p53, p57, Rb, nFkB and E2F decoys, thymidine kinase ("TK") and combinations thereof and other agents useful for interfering with cell proliferation, including agents for treating malignancies; and combinations thereof. Still other useful factors, which can be provided as polypeptides or as DNA encoding these polypeptides, include

monocyte chemoattractant protein ("MCP-1"), and the family of bone morphogenic proteins ("BMP's"). The known proteins include BMP-2, BMP-3, BMP-4, BMP-5, BMP-6 (Vgr-1), BMP-7 (OP-1), BMP-8, BMP-9, BMP-10, BMP-11, BMP-12, BMP-13, BMP-14, BMP-15, and BMP-16. Currently preferred BMPs are any of BMP-2, BMP-3, BMP-4, BMP-5, BMP-6 and BMP-7. These dimeric proteins can be provided as homodimers, heterodimers, or combinations thereof, alone or together with other molecules. Alternatively, or in addition, molecules capable of inducing an upstream or downstream effect of a BMP can be provided. Such molecules include any of the "hedgehog" proteins, or the ~~DNA's~~ DNAs encoding them.

Please amend paragraph **[0045]** of the specification as follows:

[0045] Coating materials other than therapeutic agents include, for example, polymeric materials, sugars, waxes, and fats, applied alone or in combination with therapeutic agents, and monomers that are cross-linked or polymerized. Such coating materials are applied in the form of, for example, solutions, dispersions, suspensions, and/or emulsions of one or more polymers, optionally in aqueous and/or organic solvents and combinations thereof or optionally as liquid melts including no solvents. When used with therapeutic agents, the polymeric materials are optionally applied simultaneously with, or in sequence to (either before or after), the therapeutic agents. Such polymeric materials employed as, for example, primer layers for enhancing subsequent coating applications (*e.g.*, application of alkanethiols or sulfhydryl-group containing coating solutions to gold-plated devices to enhance adhesion of subsequent layers), layers to control the release of therapeutic agents (*e.g.*, barrier diffusion polymers to sustain the release of therapeutic agents, such as hydrophobic polymers; thermal responsive polymers; pH-responsive polymers such as cellulose acetate phthalate or acrylate-based polymers, hydroxypropyl methylcellulose phthalate, and polyvinyl acetate phthalate), protective layers for underlying drug

layers (*e.g.*, impermeable sealant polymers such as ethylcellulose), biodegradable layers, biocompatible layers (*e.g.*, layers comprising albumin or heparin as blood compatible biopolymers, with or without other hydrophilic biocompatible materials of synthetic or natural origin such as dextrans, cyclodextrins, polyethylene oxide, and polyvinyl pyrrolidone), layers to facilitate device delivery (*e.g.*, hydrophilic polymers, such as polyvinyl pyrrolidone, polyvinyl alcohol, polyalkylene ~~gylcol~~ glycol (*i.e.*, for example, polyethylene glycol), or acrylate-based polymer/copolymer compositions to provide lubricious hydrophilic surfaces), drug matrix layers (*i.e.*, layers that adhere to the medical device and have therapeutic agent incorporated therein or thereon for subsequent release into the body), and epoxies.

Please amend paragraph **[0046]** of the specification as follows:

[0046] When used as a drug matrix layer for localized drug delivery, the polymer coatings of the present invention comprise any material capable of absorbing, adsorbing, entrapping, or otherwise holding the therapeutic agent to be delivered. The material is, for example, hydrophilic, hydrophobic, and/or biodegradable, and is preferably selected from the group consisting of polycarboxylic acids, cellulosic polymers, gelatin, polyvinylpyrrolidone, maleic anhydride polymers, polyamides, polyvinyl alcohols, polyethylene oxides, glycosaminoglycans, polysaccharides, polyesters, polyurethanes, silicones, polyurea, polyacrylate, polyacrylic acid and copolymers, polyorthoesters, polyanhydrides such as maleic anhydride, polycarbonates, polyethylene, polypropylenes, ~~polylatic~~ polylactic acids, polystyrene, natural and synthetic rubbers and elastomers such as polyisobutylene, polyisoprene, polybutadiene, including elastomeric copolymers, such as KRATON®, styrene-isobutylene-styrene (SIBS) copolymers; polyglycolic acids, polycaprolactones, polyhydroxybutyrate valerates, polyacrylamides, polyethers, polysaccharides such as cellulose, starch, dextran and

alginates; polypeptides and proteins including gelatin, collagen, albumin, fibrin; copolymers of vinyl monomers such as ethylene vinyl acetate (EVA), polyvinyl ethers, polyvinyl aromatics; other materials such as cyclodextrins, hyaluronic acid and phosphorylcholines; and mixtures and copolymers thereof. Coatings from polymer dispersions such as polyurethane dispersions (BAYHYDROL®, etc.) and acrylic latex dispersions are also within the scope of the present invention. In one embodiment, the polymer is polyacrylic acid available as HYDROPLUS® (Boston Scientific Corporation, Natick, Mass.), and described in U.S. Pat. No. 5,091,205, the disclosure of which is incorporated by reference herein. In other embodiments, the polymer is a co-polymer of polylactic acid and polycaprolactone; polyurethane; or an aqueous coating compositions comprising an aqueous dispersion or emulsion of a polymer having organic acid functional groups and a polyfunctional crosslinking agent having functional groups capable of reacting with organic acid groups, as described in U.S. Pat. No. 5,702,754, the disclosure of which is also incorporated herein by reference.